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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/601,875	10/12/00	TANGA	M TANGA2

001444 HM22/1220
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EXAMINER	
WILDER,C	
ART UNIT	**PAPER NUMBER**
1655	7

DATE MAILED: 12/20/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/601,875	TANGA et al.
Examiner	**Group Art Unit**
CB Wilder	1655

☒ Responsive to communication(s) filed on *Oct 12, 2000*.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-21* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-21* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☒ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. The preliminary amendment filed October 12, 2000 has been entered. Claims 1-21 are pending in the instant application.

Priority

2. Acknowledgment is made of Applicant's claim for foreign priority for Japan 10/41035, filed February 9, 1998 under 35 U.S.C. 119(a)-(d). The certified copy has been filed in the instant application.

Specification

3. The title of the invention is too wordy and confusing. A new title is required that is clearly indicative of the invention to which the claims are directed. The instant invention is drawn to a substrate and chip for immobilizing and amplifying DNA.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the Applicant regards as his invention.

5. Claim 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

(a) Claims 1-10 are indefinite at "excellent" because the term "excellent" has not been defined by the claims, the specification does not provide a standard for ascertaining the requisite meaning and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Clarification is required.

(b) Claim 5 lacks proper antecedent basis for "said polar radical" because claim 4 does not recite "a polar radical" but recites a "polar group". It is suggested amending the claims such that the claim language agree.

(c) Claims 6-8 lack proper antecedent basis for "said carboxyl radical" because claim 5 does not recite a "carboxyl radical" but recites a "carboxyl group". It is suggested amending the claims such that the claim language agree.

(d) Claims 12 and 17-20 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. The omitted steps are actual steps for amplifying DNA on a solid substrate with the addition of a primer, four nucleotide bases, a polymerase, and PCR reaction buffer as recited at page 21 of the specification. Additionally, making reference to the prior claims 1-10 and 11 is improper because those claims do not recite method steps for amplifying DNA but recite a substrate and a chip. Claims 1-10 and 11 only recite an intended use for the substrate or chip. Clarification is required.

Claim Rejections - 35 USC § 102(b)

6 The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claim 11 is rejected under 35 U.S.C. 102(b) as being anticipated by Lamture et al. (Nucleic acids Research, Vol. 22, No. 11, pages 2121-2125, December 1994). Regarding claim 11, Lamture et al. teach a chip for immobilizing DNA, wherein said chip comprises DNA immobilized on a substrate (page 2122, Figure 1, and col. 1, subheading "probe immobilization on the CCD surface"). Therefore the claimed invention of claim 11 is anticipated by the reference of Lamture et al.

Claim Rejections - 35 USC § 102(a)

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the Applicant for a patent.

9. Claim 1 is rejected under 35 U.S.C. 102(a) as being anticipated by Yoshikazu et al. (JP 09099932 A, April 15, 1997). The Applicant has claimed a solid state substrate for DNA immobilization with excellent thermal conductive characteristic for amplifying immobilized DNA. Yoshikazu et al. teach a PCR reactor comprising a solid state substrate with high thermal conductivity

for amplifying immobilized nucleic acid (Abstract). Therefore, the claimed invention is anticipated by the reference of Yoshikazu et al.

10. Claims 1, 3-5, 12, 17, and 19-21 are rejected under 35 U.S.C. 102(a) as being anticipated by Adams et al. (5,641,658, June 24, 1997). Regarding claims 1, 3-5, 12, 17 and 19-21, Adams et al. teach a method for amplifying DNA comprising immobilizing DNA on a solid substrate wherein said substrate have thermal conductive characteristics and wherein said substrate is chemically modified at a terminal with an epoxy polar group *(See Abstract* and col. 4, lines 30-48, see also Example 1). Therefore, the claimed invention of claims 1, 3-5, 12, 17, and 19-21 are anticipated by the reference of Adams et al.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) a patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made

in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

12. Claim 2 rejected under 35 U.S.C. 103(a) as being unpatentable over Yoshikazu et al. in view of Klersy et al. (5,177,567, January 5, 1993). Regarding claim 2, Yoshikazu et al. teach a solid substrate with high thermal conductivity for amplifying immobilized DNA. The method of Yoshikazu et al. differs from that of the claimed invention in that the reference does not teach wherein said substrate is a diamond. Klersy et al. teach a substrate which is fabricated with a highly thermal conductive material, such as metal wherein the substrate is insulated with diamond (col. 9, lines 22-22-26). Klersy teach that such insulated materials like diamond are characterized by relatively good thermal conductive properties so that heat is relatively efficiently transferred such that the substrate is capable of serving as a heat sink (col. 9, lines 22-32). Therefore, it would have been ***prima facie*** obvious to one of ordinary skill in the art at the time the invention was made to have modified the substrate of Yoshikazu et al. to incorporate diamond as taught by Klersy et al. for its high thermal conductive properties (col. 9, lines 22-32) as well known in the art.

13. Claims 3-7 and 13-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoshikazu et al. in view of Klersy et al. and further in view of Koster et al. (6,133,436, filing date September 1997) and in view of Nikiforov et al. (Nucleic Acids Research, May 1995) and further in view of Lamture et al. (Nucleic Acids Research, December 1994). Regarding claims 3-5 and 13-16 Yoshikazu et al. in view of Klersy et al. teach a solid state substrate for DNA immobilizing with high thermal conductive characteristics for amplifying the DNA wherein the substrate is diamond. The

substrate of Yoshikazu et al. in view of Klersy et al. differ from that of the claimed invention in that the references do not teach wherein the substrate is chemically modified such that a polar group is located at a terminal end. Koster et al. disclose a solid state substrate wherein the substrate is a flat surface or a chip (col. 4, lines 37-41) for immobilizing DNA wherein said substrate is chemically modified such that a polar group is located at a terminal end and wherein the polar group is a carboxyl group, epoxy group or amino group (col. 1, lines 58-67 and col. 2, line 1, see also col. 5, lines 35-46). Koster et al. further disclose that the functionalized polar groups allow for covalent immobilization of DNA to the solid state substrate. It would have been ***prima facie*** obvious to one of ordinary skill in the art at the time the invention was made to have modified the substrate of Yoshikazu et al. in view of Klersy et al. by chemically modifying the substrate to comprise a polar group at terminal ends for the benefit of covalently immobilizing DNA to the substrate as taught by Koster et al. (col.1, lines 55-59).

Regarding claims 6 and 7, Koster et al. teach wherein the carboxyl group is connected on a surface through an ester linkage or amide linkage (col. 5, lines 44-47 and col. 6, *Table 1*).

14. Claims 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoshikazu et al. in view of Koster et al. and further in view Uchida et al. (5,827,637, filing date March 1997). Yoshikazu et al. in view of Koster et al. teach a solid state substrate wherein the substrate is chemically modified with a polar group at a terminal end. Koster et al. teach wherein the polar groups consist of a carboxyl group, epoxy group or amino group. Koster et al. further teach wherein the functionalized polar groups allow for the covalent immobilization of DNA to the substrate. The

substrate of the claimed invention differ from that of the references in that they do not expressly teach wherein the polar group is introduced to the surface of the substrate with a cylane coupling agent, titanium coupling agent or aluminum coupling agent. Uchida et al. teach a magnetic substrate wherein the surface of the substrate is coated with a titanium coupling agent (col. 57, lines 58-59). Uchida et al. further teach wherein the coupling agent is used as a protective layer for the surface (col. 57, lines 58-61). It would have been ***prima facie*** obvious to one of ordinary skill in the art at the time the invention was made to have modified the substrate as taught by Yoshikazu et al. in view of Koster et al. with the titanium coupling agent of Uchida et al. for the benefits of providing a protective layer to the substrate as taught by Uchida et al. (col. 5, lines 58-61).

15. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Adams et al. (5,641,658, June 24, 1997) in view of Klersy et al. Regarding claim 18, Adams et al. teach a method of amplify DNA comprising immobilizing DNA on a solid substrate wherein the substrate comprise thermal conductive characteristics and wherein the substrate is chemically modified. The method and substrate of Adams differs from that of the claimed invention in that Adams to do not expressly teach wherein the substrate is diamond. Klersy et al. teach a substrate which is fabricated from a highly thermal conductive material, such as metal wherein the substrate is insulated with deposited diamond (col. 9, lines 22-22-26). Klersy further teach that such insulated materials like diamond are characterized by relatively good thermal conductive properties so that heat is relatively efficiently transferred such that the substrate is capable of serving as a heat sink (col. 9, lines 22-32). Therefore, it would have been ***prima facie*** obvious to one of ordinary skill in the art at the time the invention

was made to have modified the method of Adams et al. by incorporating the diamond substrate of Klersy et al. for its high thermal conductive properties (col. 9, lines 22-32) as well known in the art.

16. The prior art made of record is considered pertinent to Applicant's disclosure: Zhang et al. (Nucleic acids Research, December 1991) teach the covalent immobilization of DNA to a solid substrate wherein the substrate is chemically modified with a carboxyl group.

Nikiforov et al. (Analytical Biochemistry, May 1995) teach the covalent immobilization of DNA to a solid substrate wherein the substrate is chemically modified with a carboxyl group.

Conclusion

17. No claims are allowed.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Cynthia Wilder whose telephone number is (703) 305-1680. The examiner can normally be reached on Tuesday through Friday from 6:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached at (703) 308-1152. The official fax phone number for the Group is (703) 308-4242. The unofficial fax number is (703) 308-8724.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed the Group's receptionist whose telephone number is (703) 308-0196.

Cynthia Wilder

Cynthia B. Wilder, Ph.D.

December 12, 2000

M. Cary [illegible]
Supervisory Patent Examiner
Technology Center 1600

12/15/00